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Re: Public Hearing, Task Force on Drug Importation, April 14, 2004 (9am to 5pm)
Natcher Auditorium, Building 45, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892

(Docket No. 2004N-0115) Prescription Drug Importation Public Meeting

Presenter Information:

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Requested Time Allocation: 30 (Thirty) to 45 (Forty-Five) Minutes

Outline of Discussion:

(Commentary/Projections: Current Situation; Importation Phases/Impact – individual, bulk, discounted pricing; Industry Reaction; Overall Impact – Consumers/Retailers; Experiences – safety, financial; Obligations/Responsibilities of Health Care Entities)

I. **Safety Issues**
   - A. **General (product related; sourcing accountability)**
   - B. **Specific (FDA's role/ability; U.S. internal distribution system; technology)**

II. **Regulatory/Legislative Issues**
   - A. **FDA certification**
   - B. **Levels of Risk (domestic/foreign)**

III. **Technology (Improved Safety)**
   - A. **Anti-Counterfeiting**
   - B. **Costs**

IV. **Financial Impact**
   - A. **Short-Term**
   - B. **Long-Term**
   - C. **Other**

V. **R and D**
   - A. **Impact on Consumers and Patients**
   - B. **Investment**

VI. **Liability Issues**
   - A. **Bulk Importation**
   - B. **Individual Importation**
     1. **Source Accountability**
     2. **Technology**

VII. **Foreign Health Agencies**
   - A. **Reciprocity (Medical; Pharmaceutical)**
   - B. **Regulatory**